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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

GENENTECH, INC.

Plaintiff,

v.

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, a Pennsylvania non-profit corporation.

Defendant.

Case No. 5:10-CV-2037-LHK (PSG)

PLAINTIFF'S NOTICE OF MOTION AND MOTION TO COMPEL; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF

Date: May 24, 2011
Time: 10:00 a.m.
Dept: Courtroom 5, 4th Floor
Judge: Hon. Paul S. Grewal

Date Comp. Filed: May 11, 2010
Trial Date: None Set

[REDACTED – PUBLIC VERSION]

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NOTICE OF MOTION

PLEASE TAKE NOTICE that on Tuesday, May 24, 2011, at 10:00 am or as soon thereafter as the matter may be heard before The Honorable Paul S. Grewal, 280 South First Street, San Jose, California, plaintiff and counterclaim defendant Genentech, Inc. ("Genentech") will and hereby does move this Court pursuant to Federal Rule of Civil Procedure 26 for an order compelling defendants and counterclaimants the Trustees of the University of Pennsylvania ("Penn") to provide a complete and detailed response to Genentech's Interrogatory Two and to produce documents responsive to Genentech's narrowed Requests for Production Numbers 35 and 68. This motion is based on this Notice and the below Memorandum of Points and Authorities, the supporting Declaration of Sarah B. Faulkner in Support of Motion to Compel ("Faulkner Decl.") filed herewith, the reply memoranda that may be filed, the argument of counsel, the case record, and any documentary evidence that may be presented at the time of the hearing.

RELIEF REQUESTED

Genentech seeks an order compelling Penn to fully respond to Interrogatory Two by providing a detailed narrative response with citations to specific pages in the documents for support, instead of listing an undifferentiated mass of documents. Given the short window for fact discovery in the case (120 days after Judge Koh issues her Markman order), Genentech requests that Penn provide its response within five business days of this Court's order. Genentech also seeks an order compelling Penn to produce all documents from the laboratory of inventor Mark Greene that are responsive to its narrowed Requests for Production Numbers 35 and 68, which relate to the inventors' development of antibodies to p185.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Genentech filed this lawsuit to secure a declaratory judgment that use of Genentech's revolutionary cancer antibody, Herceptin, to treat breast cancer patients following surgery does not infringe Penn's US Patent Number 6,733,752 ("'752 patent") and that the '752 patent is invalid.[1] The '752 patent claims an antibody whose administration, inter alia, "inhibit[s] development into breast cancer cells of breast cells that overexpress p185." '752 patent at 8:49-51. Genentech has taken the position, consistent with contemporaneous science and the '752 patent examiner, that in humans, the only "breast cells that overexpress p185" are breast cancer cells. See Faulkner Decl. Ex. A ¶ 4; Ex. B at UP0074955 ('752 patent examiner noting that "in human[s], cells that overexpress[] p185 already are tumor cells."). Penn disputes Genentech's position, and claims that in humans, there are breast cells that overexpress p185 *other* than cancer cells and that such cells can "escape" the breast tissue and migrate to distant sites. *See* Faulkner Decl. Ex. C at 3. Penn further contends, as it must, that Herceptin acts upon these non-cancer "disseminated" cells when administered in adjuvant therapy.[2] *Id.* These contentions are the very crux of this case: should Penn be unable to show that there are breast cells in humans that overexpress p185 other than cancer cells, and in particular that such cells exist outside the breast in humans, its case would fail.

Genentech's second interrogatory asks Penn to back up its position and identify (1) human breast cells known in or before 1994 (the effective filing date of the '752 patent) that overexpress p185 but are not breast cancer cells; (2) persons knowledgeable about such cells, and (3) any supporting documents. See Faulkner Decl. Ex. D at 3-4. Notwithstanding (or

[1] Genentech has moved Judge Koh for leave to amend its pleadings to add a cause of action for unenforceability against Penn. These are no boilerplate inequitable-conduct allegations: Genentech alleges that the inventors *literally made up* the test results on which the PTO relied in granting the '752 patent and having withheld from the PTO material dosing information about the applicants' therapeutic. Genentech attaches as Exhibit E to the Faulkner Declaration its proposed First Amended Complaint, scheduled for argument on May 12 before Judge Koh.

[2] Adjuvant therapy is "treatment given to patients following surgical removal of their primary tumor and/or radiotherapy to it, when there is known to be a high risk of occult micrometastases but no clinical or radiological evidence of metastatic disease." Tannock and Hill, The Basic Science of Oncology 3rd Ed. (1998) at 498.

perhaps because of) the centrality of this interrogatory, Penn's supplemental response is a study in classic hide-the-ball: Penn merely lists the inventors, a draft manuscript of a published paper which it has never produced to Genentech, and an undifferentiated list of thousands of pages of Penn documents.

Genentech is unable to locate in this mass of documents any response to its central question: what are these non-cancer, p185 overexpressing breast cells Penn claims exist? When Genentech pressed Penn to identify where in the thousands of pages it could find an answer to this interrogatory, Penn responded that the documents "are to be read and understood as a whole." This response is as good as no response and fails to meet Penn's obligations under Federal Rule of Civil Procedure 33(d). The Court should order Penn to fully and meaningfully answer Genentech's interrogatory.

Genentech also moves this Court for an order compelling Penn to produce documents from inventor Mark Greene's laboratory relating to the development of antibodies to p185 for cancer therapeutics or prevention. Penn's initial document production suggests that the inventors may have attempted to develop effective antibodies to *human* p185, but failed. Genentech seeks the documents relating to these experiments, because they are directly relevant to proving Genentech's non-enablement and lack of written description defenses. Under well-established Federal Circuit law, an inventor's failed attempts to practice its claimed invention constitute relevant, "strong" evidence of lack of enablement. *Ormco Corp. v. Align Technology*, 498 F.3d 1307, 1319 (Fed. Cir. 2007). Genentech's narrowed Request for Production Numbers 35 and 68 are tailored to elicit evidence of such failed attempts.

Penn refuses to produce the requested documents, and has instead offered (1) the inventors' CVs, (2) "relevant" published or submitted articles, and (3) inventor grant proposals. By definition, these documents, which describe proposed experiments (grant proposals) or highlight Penn's successes (published articles), exclude the very evidence of failed experiments that would constitute strong evidence of lack of enablement. While the materials Penn offers may bear on its own infringement case, Penn cannot choose to disclose only the evidence it finds relevant and helpful to its case. Genentech respectfully requests that this Court compel Penn to

provide Genentech with documents responsive to its request.

II. FACTUAL BACKGROUND

A. Penn's claim that "breast cells that overexpress p185" exist in humans is a central infringement issue.

The '752 patent, which was filed on March 30, 1994 and lingered in prosecution before issuing a decade later on May 11, 2004, is entitled "Prevention of Tumors with Monoclonal Antibodies against NEU." *See* Complaint for Declaratory Judgment, filed on May 11, 2010 ("Complaint"), Dkt 1, Ex. A. "NEU" is a rat gene that encodes a protein called p185. The rat p185 protein has some similarities with the analogous protein found in humans, which is also called p185 or HER2. p185 is found on the surface of normal breast cells and has been correlated with breast cancer in humans when overexpressed (that is, overproduced) on the cell surface. Claim 1 of the '752 patent claims "a method of inhibiting development into breast cancer cells of breast cells that overexpress p185 in an individual in need of such inhibition," comprising various steps. (*Id.*, col. 8, lines 49-51.) These steps include the administration of an antibody "in sufficient amount to … ***inhibit the development of said breast cells that overexpress p185 into breast cancer cells***." (*Id.*, col. 8, lines 54-57) (emphasis added).

As counsel for Penn put it, a key dispute in this case concerns "what is and what is not cancer." Faulkner Decl. Ex. F at 15:16-17. Specifically, the parties vigorously dispute what cells constitute "breast cancer cells" and "breast cells that overexpress p185" under claim 1. The claim construction of both terms is under submission to Judge Koh. Genentech contends that, in humans, (1) non-cancerous "breast cells that overexpress p185" do not exist, because (2) "breast cells that overexpress p185" are already cancer cells, and thus (3) administration of the claimed antibody could not inhibit the development of these cells into breast cancer cells. *See id.* Ex. A ¶ 4. Penn alleges that "breast cells that overexpress p185" but that are ***not*** cancer do exist in humans and that Herceptin, when administered as adjuvant therapy, acts on such cells to prevent cancer, thereby infringing the '752 patent. *Id.* Ex. C at 2-3. Thus, the very existence and identity of the cells recited in claim 1 is a central infringement issue in this case.

B. Penn's refusal to answer Genentech's Interrogatory Two continues Penn's on-going resistance to disclosing a theory of infringement or Section 112 support for its alleged invention.

In light of Penn's claim that "breast cells that overexpress p185" exist in humans who have undergone surgery to remove all detectable, HER2 overexpressing breast cancer, on the second day of discovery, Genentech asked Penn in Interrogatory Two of its First Set of Interrogatories to substantiate its claim with evidence contemporaneous with the filing of the '752 patent:

> Identify anyone whom UPENN is aware of having experience or knowledge or working in the field of cancer research, diagnosis and therapy who understood in or before 1994 that human non-cancer breast cells overexpress p185; all such human non-cancer breast cell(s) known in or before 1994 to overexpress p185; any and all Persons with knowledge of such cells; and all Documents and Things supporting Your response.

Faulkner Decl. Ex. D at 3-4. On August 26, 2010, Penn responded by identifying the '752 patent inventors, the '752 patent and documents to be produced pursuant to Patent Local Rule 3-2. *Id.* Ex. G at 7. Notably, the '752 patent does not mention breast cells outside the breast, much less non-cancer breast cells in humans that overexpress p185.

After months of meet and confers, Penn finally agreed to supplement its sparse response. *See id.* Ex. H at 1. Penn's supplemental response provided little, if any, detail beyond its initial perfunctory response. Rather, on October 25, 2010, Penn merely identified the same three inventors, one "draft manuscript" addressing the same experiments on cells in the breast tissue of mice described in the '752 patent (but which has never been produced), "the '752 patent generally," "materials designated under Patent L-R 3-2," and then a mass of thousands of unexplained pages from Penn's document production. *See id* Ex. I at 2-3. As described more fully below, Penn's response fails to provide Genentech with an answer to this interrogatory or fulfill Penn's basic discovery obligations.

Penn's refusal to answer the interrogatory simply continues its pattern of hiding the ball as to what breast cells overexpress p185, and what knowledge existed of such cells as of 1994. From the beginning, Penn avoided making any identification of the first issue in its infringement contentions. Genentech met and conferred with Penn on this issue, and after Penn declined to

supplement, Genentech moved to compel in October 2010. On December 13, 2010, this Court granted Genentech's motion in relevant part, finding that Penn's infringement contentions said "nothing about where in the accused method Penn contends the 'breast cells overexpressing p185' are found." *See* Dkt. 63 at 5. The Court ordered Penn to address whether its infringement theory was directed to various "possible" cells proposed by Penn, including "'disseminated tumor cells,' 'disseminated cancer cells,' and 'cancer stem cells,'" and whether its contentions included "more than just these cells, or other cells altogether." *Id.* at 5-6.

But Penn punted again, equivocating in its amended infringement contentions that "'disseminated tumor cells,' 'disseminated cancer cells,' and 'cancer stem cells'" may or may not meet the claim limitation depending on the "HER2 overexpression status of the cell, and whether it meets or does not meet the definition of a breast cancer cell." *See* Faulkner Decl. Ex. C at 3. This answer does nothing to apprise Genentech of what cells Penn alleges are non-cancer p185 overexpressing breast cells, particularly cells that are not located in breast tissue. Moreover, it does not shed any light on the additional inquiry explicit in Interrogatory Two that is, whether there was any scientific proof of the existence of such cells as of 1994.

Even while ducking its duty to provide discovery and adequate infringement contentions, Penn has repeatedly invoked (in other contexts) its theory that such non-cancer cells exist and can be identified. For example, Penn's expert, Mark Schlissel, opined during his deposition that purported "early disseminated cells" "can escape [the breast] at many stages during the development of breast cancer over many years" but "would not meet the definition of cancers." Faulkner Decl. Ex. J at 45:12-16; *see also id.* at 45:3-5 (opining that "during the development of breast cancer, a lesion present in the breast may allow cells to escape" that may not be cancer cells).[3]

Similarly, counsel for Penn recently argued to this Court that cells that have separated

[3] When pressed to provide some support for this unorthodox theory, Dr. Schlissel stated that although he had "noticed the titles and perhaps even read abstracts of a large number of papers discussing this issue of cells escaping from developing breast lesions," he could not recall "any specific titles" – only "various authors," and "not with a degree of certainty" that would allow him to "go look them up." *Id.* at 48:19-49:6. He likewise could not "recall whether or not [any of the papers] specifically addressed the issue of whether p185 was present or not." *Id.* at 49:15-

from breast tumors and migrated to other tissues may or may not be cancer. *See id* Ex. F at 15, transcript of March 29, 2011 hearing on University of Pennsylvania's Motion to Compel (stating Genentech believes "tumor cells must be cancer" but Penn believes "there's a dispute as to what is and is not cancer"). Genentech simply seeks the evidence supporting these speculative statements, as well as any other evidence of Penn's theory that non-cancer "breast cells that overexpress p185" exist in humans, that was known to and reported by the scientific community as of the filing of the '752 patent.

C. Penn is withholding documents relevant to Genentech's defenses on unsubstantiated claims of burden.

In July and September of 2010, Genentech asked Penn to produce documents relating to the development of antibodies directed to p185, as well as documents relating to antibodies raised in inventor Greene's laboratory directed to *human* p185. See Genentech's First and Third Set of Requests for Production, Faulkner Decl. Exs. K at 10 and L at 3. Specifically, Genentech requested "All laboratory notebooks, drawings, testing records, and any other documents relating to the development of p185 antibodies, including their use for the treatment or prevention of cancer," Request for Production No. 35, and more specifically "All documents relating to the panel of antibodies raised in Dr. Greene's laboratory directed toward human HER-2 protein, including documents relating to the characterizations of these antibodies." Request for Production No. 68.[4]

Penn objected, claiming both requests were overbroad and burdensome. After numerous meet and confers, Genentech offered to narrow its document requests under Numbers 35 and 68 to a single request for:

- documents pertaining to the development, characterization and testing of p185 antibodies for use in the treatment or prevention of cancer, including documents showing competitive binding with 7.16.4 and/or down regulation of the p185 receptor

17.

[4] [redacted]

- from the laboratory of inventor of Mark Greene

See Faulkner Decl. Ex. M at 2-3. Penn continued to object, maintaining that the Greene laboratory's work beyond the experiments directly related to the '752 patent was irrelevant to this litigation and so substantial as to be overly burdensome to produce. Instead, Penn offered nothing more than the inventors' CVs, "responsive" published and submitted articles, and the inventors' p185-related grant submissions. *See id* Ex. N at 2.

Penn has likewise refused to work with Genentech to narrow these requests or provide an explanation that would allow Genentech to assess the burden of producing the documents. Genentech attempted to obtain information concerning these studies during its 30(b)(6) Deposition of Penn, but Penn's witness was totally unprepared on this issue and could not provide any information concerning antibodies directed to human p185, or the names of individuals who performed the experiments. Faulkner Decl., Ex. O; *see, e.g., id.* Ex. P at 115:6-116:8 and 193:17-194:21.

III. ARGUMENT

A. Penn continues to make every effort to avoid revealing a central infringement theory.

Genentech's Interrogatory Two addresses one of Penn's key theories of infringement: that Herceptin acts on alleged non-cancer "breast cells that overexpress p185" in humans. Penn has refused to identify the alleged cells as requested under the interrogatory, however, and instead dumped an undifferentiated list of thousands of pages of documents on Genentech.

Penn contends this list satisfies its duty under Federal Rule of Civil Procedure 33. Not so. Rule 33 requires a party relying on business records in lieu of providing factual answers to interrogatories to identify those records "in sufficient detail to permit the interrogating party to locate and identify, as readily as the party served, the records from which the answer may be obtained." *Rainbow Pioneer No. 44-18-04A v. Hawaii-Nevada Inv. Corp.*, 711 F.2d 902, 906 (9th Cir. 1983) (citing Federal Rule of Civil Procedure 33). A responding party does not fulfill this obligation, and "may not avoid answers[,] by imposing on the interrogating party a mass of business records." *L.H. v. Schwarzenegger*, 2007 WL 2781132 at *3 (E.D.Cal. 2007) (citing 7

Moore's Federal Practice, § 33.105[3] (3d ed.2001)). Here, despite numerous requests from Genentech that Penn identify which specific statements in which specific records among the thousands of cited pages contain the answer to Interrogatory Two, Penn responded only that the records "are to be read and understood as a whole." *See* Ex. N at 1. This is the very type of abuse of Rule 33 explicitly rejected by courts on a motion to compel.

Where, as here, the responding party identifies a "large block of undifferentiated documents" and "concedes that the information sought … cannot be found by reference to a single document or even by reference to a few documents," courts routinely order the responding party to "provide clear and straightforward answers … after their own evaluation of the documents." *E. & J. Gallo Winery v. Cantine Rallo*, 2006 WL 3251830 at *3 (E.D.Cal. 2006); *see also L.H. v. Schwarzenegger*, 2007 WL 2781132 at *3 ("If the party cannot identify which specific documents contain the answer to the interrogatories, they must completely answer the interrogatories without referring to the documents.")

Penn's response leaves Genentech wondering whether Penn is simply not aware of any facts to support one of its central infringement contentions, or its strained interpretation of its own patent, or whether this tactic is designed to bury those facts. Given that Penn, through its expert and counsel, has made numerous but oblique references to the existence of human breast cells that overexpress p185 but are not cancer cells, Penn has an obligation to disclose the identity and location of these cells and any support for their existence as of the filing date of the patent. *See, e.g.*, Faulkner Decl. Ex. J at 45-49 (Penn's expert, Dr. Schlissel, stating that a "large number of papers" discuss early disseminated cells from the breast that are not cancer cells, but failing to identify **any** such papers); *see also id* Ex. F at 15 (Penn's counsel stating Genentech believes "that all tumor cells must be cancer" but Penn believes "there's a dispute as to what is and is not cancer"). Accordingly, Genentech requests that this Court compel Penn to provide a full, straightforward, narrative answer to this critical interrogatory, including a recitation of any scientific publication as of March 1994 that referred to such cells and/or identified where they can be found; a specific recitation of any text in a Penn internal document that refers to such cells; an identification of any individual other than the inventors who allegedly knew about such

cells; and an explanation of what knowledge such individual(s) had as of the patent filing date.

B. Penn is withholding documents that are directly relevant to Genentech's enablement and written description defenses.

It is well-established that an inventor's failed attempts to practice its claimed invention constitute relevant, "strong" evidence of lack of enablement. *Ormco Corp.*, 498 F.3d at 1319; *see also Novo Nordisk Pharmaceuticals, Inc. v. Bio-Tech. General Corp.*, 424 F.3d 1347, 1362 (Fed. Cir. 2005) ("[A]n inventor's failed attempts to practice an invention are relevant evidence of non-enablement."). Genentech's narrowed document request seeks this relevant evidence. Penn's selective disclosure, which seems to account only for documents needed to prove its own infringement case, must be rejected for two reasons.

First, in seeking to limit its production to proposed experiments in grant applications and publishable-quality articles, Penn has restricted its disclosure, by definition, to successful experiments—which is ***not*** what Genentech seeks. Failed experiments and any related results and data would be found in laboratory notebooks and bench materials – the very information that Penn refuses to produce. ***Second***, the '752 patent claims a broad genus of antibodies that potentially includes far more antibodies than those disclosed in the few studies Penn unilaterally deemed relevant here. For example, the '752 patent claims an antibody that can prevent cancer in any mammalian species having "breast cells that overexpress p185" – be it mice, rats or humans.[5] However, the only antibody disclosed in the '752 patent that possibly falls within the claimed genus and meets the required criteria under claim 1 is antibody 7.16.4. Those skilled in the art in 1993 and 1994, however, understood that antibody 7.16.4 did not bind to human or mouse p185 in a therapeutically sufficient amount.[6] Likewise, when asked in discovery to identify each and every antibody that meets the limitations of claim 1 in any mammalian cells,

[5] Claim 1 of the '752 patent further requires the antibody "compete[] with an antibody produced by cell line ATCC Deposit No. 10493 for binding to p185," "bind to p185 in sufficient amount to down regulate the overexpressed p185," and "inhibit the development of [] breast cells that overexpress p185 into breast cancer cells."

[6] [redacted]

Penn identified only Herceptin. *See* Faulkner Decl. Ex Q at 2-3. Thus, the documents Genentech seeks by its request would provide the only evidence in this litigation showing whether the inventors ever had possession of an antibody other than 7.16.4 that falls within the scope of claim 1, and if so, how much time and experimentation was required to develop such an antibody.

This request is not a fishing expedition. In fact, Genentech has every reason to believe the inventors conducted experiments relevant to its non-enablement and lack of written description defenses. Simply by way of example, in a 1993 application for continuing grant funds, inventor Greene represented that:

[redacted] *See id* Ex. S at UP0005727 and UP0005870. The experiments underlying these studies are directly relevant to showing whether the inventors tried (and failed) to create antibodies covered by the '752 patent.

Penn refuses to produce these documents solely on the basis of burden. However, it has never provided ***any*** explanation of the purported burden of producing these human p185 studies, nor has it identified the number of individuals who worked on these studies so that Genentech may properly assess the burden. Further, Genentech ***has tried*** to obtain this type of information

through its 30(b)(6) Deposition of Penn. But Penn's 30(b)(6) witness, Gail Massey, was woefully unprepared to provide any information concerning use of 7.16.4 or any other antibodies directed to human p185, or the names of individuals who performed the experiments.[7] *See, e.g.*, Faulkner Decl. Ex. P at 115:6-116:8 and 193:17-194:21; see also id Ex. O. Penn has thwarted Genentech's every attempt to discover information concerning these studies, and the time for fact discovery is waning. Accordingly, Genentech moves this court to compel Penn to provide the documents responsive to its narrowly tailored request so that Genentech may adequately prepare its enablement and written description defenses.

IV. CONCLUSION

For the foregoing reasons, Genentech respectfully requests this Court compel Penn to (1) fully respond to Interrogatory Two by providing a full narrative response with citations to specific page numbers in the documents for support as described above; and (2) produce all documents responsive to Genentech's narrowed document request identified herein, which addresses Genentech's Request for Production Numbers 35 and 68.

[7] Genentech reserves the right to move to compel further testimony on each of the 30(b)(6) topics, 1-3, 5 and 7, for which Gail Massey was designated. *See* Faulkner Decl Ex. U.

Dated: April 19, 2011

By: */s/ Sarah B. Faulkner*

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